

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

MOUNT SINAI SCHOOL OF MEDICINE)
OF NEW YORK UNIVERSITY,)
One Gustave L. Levy Place, New York, NY)
10029,)

Plaintiff,)

v.)

HONORABLE DAVID J. KAPPOS)
Under Secretary of Commerce for)
Intellectual Property and)
Director of the United States Patent and)
Trademark Office,)
Office of the General Counsel,)
United States Patent and Trademark Office)
P.O. Box 15667, Arlington, VA 22215)
Madison Building East, Room 10B20)
600 Dulany Street, Alexandria, VA 22314,)

Defendant.)

CIVIL ACTION NO. _____

COMPLAINT

Mount Sinai School of Medicine of New York University ("Mount Sinai"), for its complaint against the Honorable David J. Kappos ("Defendant"), states as follows:

1. Mount Sinai, the owner of United States Patent No. 7,588,768 ("768 patent"), seeks review of an erroneous patent term adjustment determination by the United States Patent and Trademark Office ("USPTO"). Mount Sinai particularly seeks judgment that the patent term adjustment be changed from the USPTO's determination of 166 days to 742 days.

2. This action arises under 35 U.S.C. § 154 and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

THE PARTIES

3. Mount Sinai is a not-for-profit corporation organized under the laws of New

York, with a principal place of business at One Gustavè L. Levy Place, New York, NY 10029.

4. Defendant is the Under Secretary of Commerce for Intellectual Property and Director of the USPTO, and is being sued here in his official capacity.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action and is authorized to issue the requested relief pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1361, 35 U.S.C. § 154(b)(4)(A), and 5 U.S.C. §§ 701-706.

6. Venue is proper in this district by virtue of 35 U.S.C. § 154(b)(4)(A).

7. This Complaint is being timely filed in accordance with 35 U.S.C. § 154(b)(4)(A) and Fed. R. Civ. P. 6(a).

FACTS

8. On November 14, 2003, Peter Palese, Adolfo Garcia-Sastre, and Thomas Muster ("Applicants") filed patent application number 10/713,732 ("732 application"). See '768 patent at 1, attached as Exhibit A (cover page only of the '768 patent).

9. On September 6, 2006, the USPTO mailed the first notification under 35 U.S.C. § 132, a restriction requirement regarding the '732 application.

10. On March 23, 2007, Applicants filed an amendment under 37 C.F.R. § 1.111 in response to an office action mailed by the USPTO on October 24, 2006.

11. On November 14, 2007, Applicants filed a notice of appeal from the decision in an office action mailed by the USPTO on May 15, 2007.

12. On April 11, 2008, Applicants filed a request for continued examination ("RCE") under 35 U.S.C. § 132(b).

13. On December 2, 2008, Applicants filed an amendment under 37 C.F.R. § 1.111 in

response to an office action mailed by the USPTO on July 2, 2008.

14. On March 4, 2009, Applicants filed a supplemental information disclosure statement under 37 C.F.R. §§ 1.56 and 1.97.

15. On March 13, 2009, the USPTO mailed a notice of allowance in the '732 application.

16. On May 7, 2009, Applicants filed a petition under 37 C.F.R. § 1.59.

17. On May 12, 2009, the USPTO mailed a decision on Applicants' petition under 37 C.F.R. § 1.59.

18. On July 14, 2009, Applicants filed a miscellaneous letter relating to the '732 application.

19. On September 15, 2009, the '732 application issued as the '768 patent.

20. The '768 patent is not subject to a terminal disclaimer.

21. Mount Sinai is the assignee of all right, title and interest in the '768 patent, as evidenced by records on deposit with the USPTO.

22. The cover page of the '768 patent indicates a patent term adjustment under 35 U.S.C. § 154(b) of 166 days, as determined by the USPTO. *See* Exhibit A; *see also* USPTO PAIR Adjustment, attached as Exhibit B.

23. On June 12, 2009, Applicants timely filed a first request for reconsideration of patent term adjustment under 37 C.F.R. § 1.705(b) ("First Request") with the USPTO seeking to correct errors in the Director's patent term adjustment determination for the '768 patent. A copy of the First Request is attached as Exhibit C (request only without exhibits).

24. On August 13, 2009, the USPTO mailed a decision dismissing Applicants' First Request as premature. A copy of this decision is attached as Exhibit D.

25. On November 16, 2009, Applicants timely filed a revised request for reconsideration of patent term adjustment under 37 C.F.R. § 1.705(b) ("Revised Request") with the USPTO seeking to correct errors in the Director's patent term adjustment determination for the '768 patent. Specifically, Applicants requested a patent term adjustment for the '768 patent totaling 742 days. A copy of the Revised Request is attached as Exhibit E (request only without exhibits). The USPTO to date has not responded to Applicants' Revised Request.

26. Title 35 U.S.C. § 154(b) requires adjustment of patent terms to compensate for failures of the USPTO to take certain actions on patent applications within designated time limits. Title 35 U.S.C. § 154(b)(3) requires the Director of the USPTO to determine the patent term adjustment for each patent.

27. In calculating the patent term adjustment, the Director must account for USPTO delays under 35 U.S.C. § 154(b)(1), any overlapping delay periods in the USPTO delays under 35 U.S.C. § 154(b)(2)(A), and any applicant delays under 35 U.S.C. § 154(b)(2)(C).

28. Under 35 U.S.C. § 154(b)(4)(A), "[a]n applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such action."

CLAIM FOR RELIEF

29. The allegations of paragraphs 1-28 are incorporated in this claim for relief as if fully set forth herein.

30. The USPTO determined that the total patent term adjustment for the '768 patent is 166 days. This patent term adjustment determination is in error.

31. Under 35 U.S.C. § 154(b)(1)(A), the USPTO delayed the examination of the '732

application for a period of 600 days (the “A Delay”). The 600-day period of A Delay is due to the USPTO’s failure to mail a notification under 35 U.S.C. § 132 not later than fourteen months from the filing date of the ’732 application.

32. The USPTO does not dispute that it mailed the first notification under 35 U.S.C. § 132, a restriction requirement, on September 6, 2006, a period of fourteen months and 600 days after the filing of the ’732 application on November 14, 2003. *See* Exh. B at 2-3.

33. Under 35 U.S.C. § 154(b)(1)(B), the USPTO delayed the examination of the ’732 application for a period of 514 days (the “B Delay”). The 514-day period of B Delay is due to the USPTO’s failure to issue the ’768 patent within three years from the filing date of the ’732 application, not including the days consumed by continued examination requested by Applicants under 35 U.S.C. § 132(b).

34. The USPTO does not dispute that the ’732 application was pending from its filing date on November 14, 2003, to the date on which Applicants filed a RCE, April 11, 2008, a period of three years and 514 days. *See* Exh. B at 2-3.

35. Thus, the total period of USPTO delay for the ’768 patent is 1,114 days, which is the sum of the 600 days of A Delay and the 514 days of B Delay.

36. Under 35 U.S.C. § 154(b)(2)(A), “[t]o the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.”

37. Here, the periods of delay attributable to the USPTO do not overlap. The 600-day period of A Delay from January 15, 2005, to September 6, 2006, does not overlap the 514-day period of B Delay from November 15, 2006, to April 11, 2008. *See Wyeth v. Kappos*, 591 F.3d 1364, 1370 (Fed. Cir. 2010) (“If an A delay occurs on one day and a B delay occurs on a

different day, those two days do not ‘overlap’ under section 154(b)(2).”). Thus, the delay applicable to the USPTO is 600 days plus 514 days for a total of 1,114 days.

38. Under 35 U.S.C. § 154(b)(2)(C), the total period of USPTO delay is reduced by the period of applicant delay. Here, 372 days of delay are attributable to Applicants.

39. First, 58 days of applicant delay accrued when Applicants filed an amendment on March 23, 2007, three months and 58 days after the USPTO mailed an office action on October 24, 2006. *See* 35 U.S.C. § 154(b)(2)(C)(ii) (defining applicant delay as “any periods of time in excess of 3 months that are taken to respond to a notice from the Office . . . from the date the notice was given or mailed to the applicant.”). The USPTO agrees with this calculation of 58 days of applicant delay. *See* Exh. B at 2.

40. Second, 91 days of applicant delay accrued when Applicants filed a notice of appeal on November 14, 2007, three months and 91 days after the USPTO mailed an office action on May 15, 2007. *See* 35 U.S.C. § 154(b)(2)(C)(ii). The USPTO agrees with this calculation of 91 days of applicant delay. *See* Exh. B at 2.

41. Third, 61 days of applicant delay accrued when Applicants filed an amendment on December 2, 2008, three months and 61 days after the USPTO mailed an office action on July 2, 2008. *See* 35 U.S.C. § 154(b)(2)(C)(ii). The USPTO agrees with this calculation of 61 days of applicant delay. *See* Exh. B at 1.

42. Fourth, 92 days of applicant delay accrued when Applicants filed a supplemental information disclosure statement on March 4, 2009, 92 days after Applicants filed an amendment on December 2, 2008. *See* 35 U.S.C. § 154(b)(2)(C)(iii) (stating that the Director of the USPTO shall prescribe regulations regarding applicant delay); 37 C.F.R. § 1.704(c)(8) (defining applicant delay as the submission of a supplemental paper not expressly requested by the

examiner after filing an initial reply, and setting forth the period of delay as “beginning on the day after the date the initial reply was filed and ending on the date that the supplemental . . . paper was filed”). The USPTO agrees with this calculation of 92 days of applicant delay. *See* Exh. B at 1.

43. Fifth, 6 days of applicant delay accrued between May 7, 2009, the date Applicants filed a petition after a notice of allowance, and May 12, 2009, the date the USPTO mailed a decision on the petition. *See* 35 U.S.C. § 154(b)(2)(C)(iii); 37 C.F.R. § 1.704(c)(10) (defining applicant delay as the number of days beginning on the date an applicant files a paper after a notice of allowance and ending on the mailing date of a notice from the USPTO in response to the paper). The USPTO agrees that Applicants filed a petition on May 7, 2009, and that the USPTO mailed a decision in response to the petition on May 12, 2009. *See* Exh. B at 1. However, by continuing its calculation of applicant delay beyond May 12, 2009, the USPTO incorrectly calculated 68 days of applicant delay in connection with Applicants’ petition. *See* Exh. B at 1.

44. Sixth, 64 days of applicant delay accrued between July 14, 2009, the date Applicants filed a miscellaneous letter relating to the ’732 application, and September 15, 2009, the date the ’768 patent issued. *See* 37 C.F.R. § 1.704(c)(10). The USPTO agrees with this calculation of 64 days of applicant delay. *See* Exh. B at 1.

45. Thus, the total period of applicant delay for the ’768 patent is 372 days, which is the sum of the six periods of applicant delay described above.

46. In summary, the correct patent term adjustment for the ’768 patent is 742 days, which is the sum of the 600 days of A Delay and the 514 days of B Delay, minus the 372 days of applicant delay.

PRAYER FOR RELIEF

WHEREFORE, Mount Sinai respectfully prays that this Court:

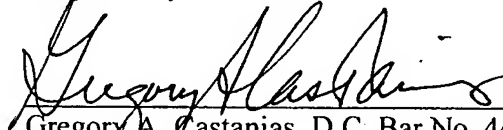
A. Issue an order changing the period of patent term adjustment for the '768 patent from 166 days to 742 days, and requiring Defendant to alter the term of the '768 patent to reflect the 742 days of actual patent term adjustment;

B. Issue an order requiring Defendant to correct the front page of the '768 patent, issue a Certificate of Correction, or otherwise take action to reflect on the '768 patent the 742 days of actual patent term adjustment; and

B. Grant such other and further relief as the nature of the case may admit or require and as may be just and equitable.

Dated: March 12, 2010

Respectfully submitted,



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Attorneys for Plaintiff
MOUNT SINAI SCHOOL OF MEDICINE
OF NEW YORK UNIVERSITY

Exhibit A



US007588768B2

(12) **United States Patent**
Palese et al.

(10) **Patent No.:** **US 7,588,768 B2**
(45) **Date of Patent:** **Sep. 15, 2009**

(54) **ATTENUATED NEGATIVE STRAND VIRUSES WITH ALTERED INTERFERON ANTAGONIST ACTIVITY FOR USE AS VACCINES AND PHARMACEUTICALS**

(75) Inventors: **Peter Palese, Leonia, NJ (US); Adolfo Garcia-Sastre, New York, NY (US); Thomas Muster, Vienna (AT)**

(73) Assignee: **Mount Sinai School of Medicine of New York University, New York, NY (US)**

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 166 days.

(21) Appl. No.: **10/713,732**

(22) Filed: **Nov. 14, 2003**

(65) **Prior Publication Data**

US 2004/0109877 A1 Jun. 10, 2004

Related U.S. Application Data

(63) Continuation of application No. 09/332,288, filed on Jun. 11, 1999, now Pat. No. 6,669,943.

(60) Provisional application No. 60/117,683, filed on Jan. 29, 1999, provisional application No. 60/108,832, filed on Nov. 18, 1998, provisional application No. 60/089,103, filed on Jun. 12, 1998.

(51) **Int. Cl.**

A61K 39/38 (2006.01)

A61K 39/12 (2006.01)

A01N 63/00 (2006.01)

A61K 39/145 (2006.01)

A61K 39/25 (2006.01)

(52) **U.S. Cl.** **424/206.1; 424/199.1; 424/209.1; 424/184.1; 424/93.6**

(58) **Field of Classification Search** **424/206.1, 424/209.1, 281.1, 93.1, 93.2; 435/235.1, 435/236**

See application file for complete search history.

(56) **References Cited**

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(Continued)

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(Continued)

Primary Examiner—Bruce Campell
Assistant Examiner—Benjamin P Blumel
(74) *Attorney, Agent, or Firm*—Jones Day

(57) **ABSTRACT**

The present invention relates, in general, to attenuated negative-strand RNA viruses having an impaired ability to antagonize the cellular interferon (IFN) response, and the use of such attenuated viruses in vaccine and pharmaceutical formulations. The invention also relates to the development and use of IFN-deficient systems for selection of such attenuated viruses.

In particular, the invention relates to attenuated influenza viruses having modifications to the NS1 gene that diminish or eliminate the ability of the NS1 gene product to antagonize the cellular IFN response. The mutant viruses replicate in vivo but demonstrate reduced pathogenicity, and therefore are well suited for live virus vaccines, and pharmaceutical formulations.

37 Claims, 3 Drawing Sheets

Exhibit B

10/713,732	ATTENUATED NEGATIVE STRAND VIRUSES WITH ALTERED INTERFERON ANTAGONIST ACTIVITY FOR USE AS VACCINES AND PHARMACEUTICALS	03-11- 2010::18:19:43
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Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/713,732

Filing or 371(c) Date:	11-14-2003	USPTO Delay (PTO) Delay (days):	-
Issue Date of Patent:	09-15-2009	Three Years:	-
Pre-Issue Petitions (days):	-	Applicant Delay (APPL) Delay (days):	-
Post-Issue Petitions (days):	-	Total PTA (days):	166
USPTO Adjustment(days):	-	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
08-26-2009	PTA 36 Months		
09-15-2009	Patent Issue Date Used in PTA Calculation		
08-20-2009	Dispatch to FDC		
08-20-2009	Dispatch to FDC		
08-13-2009	Mail-Petition Decision - Dismissed		
08-13-2009	Petition Decision - Dismissed		
07-14-2009	Miscellaneous Incoming Letter		64
06-12-2009	Petition Entered		↑
06-15-2009	Application Is Considered Ready for Issue		↑
06-12-2009	Issue Fee Payment Verified		↑
06-12-2009	Statement Filed Indicating a Loss of Entitlement to Small Entity Status		↑
06-12-2009	Issue Fee Payment Received		↑
05-07-2009	Miscellaneous Incoming Letter		68
05-12-2009	Mail-Petition Decision - Granted		↑
05-12-2009	Petition Decision - Granted		↑
05-07-2009	Petition Entered		↑
03-13-2009	Mail Notice of Allowance		↑
03-12-2009	Document Verification		↑
03-12-2009	Notice of Allowance Data Verification Completed		↑
03-12-2009	Case Docketed to Examiner in GAU		↑
03-12-2009	Examiner's Amendment Communication		↑
03-04-2009	Reference capture on IDS		↑
03-04-2009	Information Disclosure Statement (IDS) Filed		92
03-04-2009	Information Disclosure Statement considered		↑
03-04-2009	Information Disclosure Statement (IDS) Filed		↑
01-12-2009	Date Forwarded to Examiner		↑
12-02-2008	Response after Non-Final Action		61
12-02-2008	Request for Extension of Time - Granted		↑
07-02-2008	Mail Non-Final Rejection		↑
07-01-2008	Non-Final Rejection		

06-25-2008	Examiner Interview Summary Record (PTOL - 413)	
04-11-2008	Information Disclosure Statement considered	
04-23-2008	Oath or Declaration Filed (Including Supplemental)	
04-11-2008	Information Disclosure Statement (IDS) Filed	
04-26-2008	Date Forwarded to Examiner	
04-26-2008	Date Forwarded to Examiner	
04-11-2008	Request for Continued Examination (RCE)	
04-26-2008	Disposal for a RCE / CPA / R129	
04-11-2008	Request for Extension of Time - Granted	
04-11-2008	Information Disclosure Statement (IDS) Filed	
04-11-2008	Workflow - Request for RCE - Begin	
11-14-2007	Notice of Appeal Filed	91
11-14-2007	Request for Extension of Time - Granted	↑
11-15-2007	Miscellaneous Incoming Letter	↑
10-19-2007	Mail Examiner Interview Summary (PTOL - 413)	↑
03-08-2007	Examiner Interview Summary Record (PTOL - 413)	↑
05-15-2007	Mail Final Rejection (PTOL - 326)	↑
05-14-2007	Final Rejection	
03-23-2007	Information Disclosure Statement considered	
05-02-2007	Case Docketed to Examiner in GAU	
03-23-2007	Reference capture on IDS	
03-23-2007	Information Disclosure Statement (IDS) Filed	
03-23-2007	Information Disclosure Statement (IDS) Filed	
04-19-2007	Date Forwarded to Examiner	
03-23-2007	Response after Non-Final Action	58
03-23-2007	Request for Extension of Time - Granted	↑
01-17-2007	Case Docketed to Examiner in GAU	↑
10-24-2006	Mail Non-Final Rejection	↑
10-23-2006	Non-Final Rejection	
11-14-2003	Information Disclosure Statement considered	
10-19-2006	Date Forwarded to Examiner	
10-06-2006	Response to Election / Restriction Filed	
09-06-2006	Mail Restriction Requirement	600
09-05-2006	Requirement for Restriction / Election	↑
11-23-2005	IFW TSS Processing by Tech Center Complete	↑
11-14-2003	Reference capture on IDS	↑
05-21-2004	Case Docketed to Examiner in GAU	↑
11-14-2003	Information Disclosure Statement (IDS) Filed	↑
11-14-2003	Information Disclosure Statement (IDS) Filed	↑
11-14-2003	Preliminary Amendment	↑
03-04-2004	Application Return from OIPE	↑

03-04-2004	Application Return TO OIPE	↑
03-04-2004	Application Dispatched from OIPE	↑
03-04-2004	Application Is Now Complete	↑
02-24-2004	Cleared by L&R (LARS)	↑
02-02-2004	Referred to Level 2 (LARS) by OIPE CSR	↑
12-22-2003	IFW Scan & PACR Auto Security Review	↑
11-14-2003	Initial Exam Team nn	↑

Close Window

Exhibit C

Electronically filed

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Palese et al.	Confirmation No.:	3723
Serial No.:	10/713,732	Art Unit:	1648
Filed:	November 14, 2003	Examiner:	Blumel, Benjamin P.
For:	ATTENUATED NEGATIVE STRAND VIRUSES WITH ALTERED INTERFERON ANTAGONIST ACTIVITY FOR USE AS VACCINES AND PHARMACEUTICALS	Attorney Docket No:	6923-118

**REQUEST FOR RECONSIDERATION OF
PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)**

MAIL STOP ISSUE FEE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants received a Notice of Allowance, mailed March 13, 2009, from the United States Patent and Trademark Office ("PTO") in connection with Application No. 10/713,732 (hereinafter "the '732 application"), together with a Determination of Patent Term Adjustment under 35 U.S.C. 154(b) stating that the projected patent term adjustment to date is 298 days.

Applicants hereby respectfully request reconsideration of the patent term adjustment indicated in the Determination of Patent Term Adjustment under 35 U.S.C. 154(b) ("Determination") mailed March 13, 2009. Specifically, Applicants believe that the patent term adjustment of 298 days is not correct. The correct number of days for the patent term adjustment, for reasons explained below, should be, at a minimum, equal to the period starting January 14, 2005 and ending September 6, 2006 (600 days) plus the period starting November 15, 2006 and ending on April 11, 2008, the date that a request for continued examination (RCE) was filed (estimated to be 514 days) (see 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1)), minus 302 days consumed by Applicant delay (see 37 C.F.R. § 1.704(b)). For

Request for Reconsideration of Patent Term Adjustment Under 37 C.F.R. § 1.705(b)
Application No. 10/713,732

the purpose of this Request, Applicants assume that the patent will issue on the '732 application on October 6, 2009, which is the Tuesday before the date that is four months after the mailing date of the issue fee payment, which accompanies this Request. Therefore, Applicants believe that the patent term adjustment should be, at a minimum, a total of 812 days.

A request for reconsideration of patent term adjustment under 37 C.F.R. § 1.705(b) must be accompanied by:

- (1) the fee set forth in 37 C.F.R. § 1.18(e); and
- (2) a statement of the facts involved, specifying:
 - (i) the correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment;
 - (ii) the relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) to which the patent is entitled;
 - (iii) whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and
 - (iv)(A) any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704; or
(B) that there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704.

See 37 C.F.R. § 1.705(b).

In support of this request, Applicants submit the following statement of facts:

1. Fee Required Under 37 C.F.R. § 1.705(b)(1)

Pursuant to 37 C.F.R. §§ 1.705(b)(1) and § 1.18(e), the fee required for filing this application is believed to be \$200.00.

Please charge the required fee to Jones Day Deposit Account No. 50-3013 (referencing 702827-999117).

Request for Reconsideration of Patent Term Adjustment Under 37 C.F.R. § 1.705(b)
Application No. 10/713,732

2. Statement Required Under 37 C.F.R. § 1.705(b)(2)

Pursuant to 37 C.F.R. § 1.702, Applicants submit the following statement of facts in support of this application:

- (i) The correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment are as follows:

1. Correct patent term adjustment:

The correct patent term adjustment is 812 days, assuming that the patent will issue on the above-identified application on October 6, 2009, which is attributable to (a) the failure of the PTO to mail a notification under 35 U.S.C. § 132 not later than fourteen months after the date on which the '732 application was filed under 35 U.S.C. 111(a) (delay under 37 C.F.R. § 1.702(a)(1)) (the "A period") minus the number of actual calendar days occurring in both the A period and in the "B period" described below; and (b) the failure of the PTO to issue a patent within three years of the actual filing date of the '732 application (delay under 37 C.F.R. § 1.702(b)) (the "B period"), and minus the time consumed by Applicant delay as provided for in 37 C.F.R. § 1.704(b).

2. Bases under 37 C.F.R. § 1.702 for the adjustment:

(a) Delay under 37 C.F.R. § 1.702(a) (the "A period")

The delay by the PTO under 37 C.F.R. § 1.702(a) is 600 days.

As acknowledged by the PTO in its calculation of the patent term adjustment, the PTO failed to mail a notification under 35 U.S.C. § 132 within fourteen months from the date of filing of the '732 application. See PTO's Patent Application Information Retrieval page for U.S. Application No. 10/713,732 at Patent Term Adjustment History ("PTO PAIR Adjustment," Exhibit A, downloaded June 11, 2009). The '732 application was filed under 35 U.S.C. § 111(a) on November 14, 2003. The first notification under 35 U.S.C. § 132 (a Restriction Requirement) was mailed by the PTO on September 6, 2006. Accordingly, the PTO did not mail a notification under 35 U.S.C. § 132 or a notice of allowance under 35 U.S.C. § 151 within fourteen months after the date on which the application was filed (*i.e.*, by January 14, 2005), and thus, assuming that the patent will issue on the above-identified application on or before October 6, 2009, the delay under 37 C.F.R. § 1.702(a)(1) includes 600 days.

Request for Reconsideration of Patent Term Adjustment Under 37 C.F.R. § 1.705(b)
Application No. 10/713,732

In sum, the number of days of delay in the A period, that is, under subsection (a)(1) of 37 C.F.R. § 1.702 is, at a minimum, 600 days.

(b) Delay under 37 C.F.R. § 1.702(b) (the "B period")

The delay by the PTO under 37 C.F.R. § 1.702(b) is 514 days.

The '732 application was filed under 35 U.S.C. § 111(a) on November 14, 2003. A patent has not yet issued, however, an Issue Fee payment authorization accompanies this Request. As provided for under 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1), the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed, not including the number of days in the period beginning on the date on which an RCE was filed and ending on the date the patent was issued. Therefore, in this case, the "B period" begins on November 15, 2006 and ends on April 11, 2008, the date that an RCE was filed (514 days). This delay in issuance of the patent was not included by the PTO in its calculation of patent term adjustment (*see* "PTO PAIR Adjustment," Exhibit A). Therefore, the total patent term adjustment for delay in issuance of the patent under the B period is 514 days.

(c) Overlapping Days in the Delay Periods

According to 35 U.S.C. § 154(b)(2)(A): "To the extent that periods of delay attributable to grounds specified in paragraph (1) *overlap*, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." *See* 35 U.S.C. § 154(b)(2)(A).

Applicants submit that there was no overlap of the actual calendar days of the A period, discussed in detail below, with the actual calendar days of the B period. Thus, the period of patent term adjustment on a patent that issues on the above-identified patent application is calculated as the sum of 600 plus 514, which is equal to 1,114 days (minus the time consumed by Applicant delay as discussed in Section ii below).

Applicants respectfully submit that under controlling case law, calculating the patent term adjustment is the result of summing the number of days of delay under 37 C.F.R. § 1.702(a) that do not comprise actual calendar days occurring in the B period (that is, the A period minus calendar days overlapping in both the A and B periods) and the number of days of delay under 37 C.F.R. § 1.702(b) (the B period). *See Wyeth v. Dudas*, 580 F.Supp.2d 138 (D.D.C. 2008) (hereinafter *Wyeth*), a copy of which is included here as Exhibit B.

Request for Reconsideration of Patent Term Adjustment Under 37 C.F.R. § 1.705(b)
Application No. 10/713,732

In *Wyeth*, the Court held that “the only way that periods of time can ‘overlap’ is if they occur on the same day [and thus, if] an ‘A delay’ occurs on one calendar day and a ‘B delay’ occurs on another, they do not overlap.”

Turning to the '732 application, the period of delay under subsection (a)(1) of 37 C.F.R. § 1.702 includes the days of January 15, 2005 to September 6, 2006 (600 days). The delay under 37 C.F.R. § 1.702(b) comprises November 15, 2006 to April 11, 2008, the day on which an RCE was filed (514 days). Thus, the delay under 37 C.F.R. § 1.702(a)(1) occurring from January 15, 2005 to September 6, 2006 occurred on different calendar days than the delay under 37 C.F.R. § 1.702(b) (November 15, 2006 to April 11, 2008). Consequently, under 35 U.S.C. § 154(b)(2)(A), there are 600 days under 37 C.F.R. § 1.702(a) that do not overlap the 514 days of delay under 37 C.F.R. § 1.702(b) for the '732 application, and therefore the total delay under 37 C.F.R. § 1.702 for the adjustment should be a summation of the delays under 37 C.F.R. § 1.702(a) and 37 C.F.R. § 1.702(b), or 1,114 days (the sum of 600 and 514 days), assuming that the patent on the '732 application issues on Tuesday, October 6, 2009, which is the Tuesday before the date that is four months after the mailing date of the issue fee payment, which accompanies this Request.

- (ii) The relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) and 37 C.F.R. § 1.704(b) are as follows:

1. Adjustment under 37 C.F.R. §§ 1.703(a) through (e):

An adjustment is sought under 37 C.F.R. § 1.703(a)(1), which provides, in relevant part, that the period of adjustment is “[t]he number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first.” In particular, Applicants seek to include the delay under 37 C.F.R. § 1.702(a)(1) occurring from January 15, 2005 to September 6, 2006 (600 days) that occurred on different calendar days than the delay under 37 C.F.R. § 1.702(b).

An adjustment is sought under 37 C.F.R. § 1.703(b), which provides, in relevant part, that “the period of adjustment under 37 C.F.R. § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a)...and ending on the date a patent was issued . .

Request for Reconsideration of Patent Term Adjustment Under 37 C.F.R. § 1.705(b)
Application No. 10/713,732

not including . . . [t]he number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date the patent was issued.”

Applicants submit that this period consists of 514 days for the period beginning the day after November 14, 2006 (the date that is three years after the date on which the '732 application was filed) and ending on the day that an RCE was filed, April 11, 2008.

Applicants further submit that the 600 actual calendar days of delay under 37 C.F.R. § 1.702(a) do not overlap the any of the 514 actual calendar days of delay under 37 C.F.R. § 1.702(b), as explained above.

Accordingly, Applicants believe that the delays attributable to PTO delay under 37 C.F.R. § 1.702 total 1,114 days.

2. Adjustment under 37 C.F.R. § 1.704(b):

As discussed in section (i) above, Applicants believe that the total delay by the PTO under 37 C.F.R. § 1.702(a) and (b) amounts to 1,114 days. Applicants believe that there was a period of 302 days constituting a delay attributable to Applicants under 37 C.F.R. § 1.704(b). Therefore, assuming that the patent on the '732 application issues on or before October 6, 2009, Applicants believe that the total period of adjustment due under 37 C.F.R. § 1.703(f) is 812 days, not the 298 days calculated by the PTO. This total period is the sum of the periods of delay by the PTO calculated under 37 C.F.R. §§ 1.702(a) through (e) (*i.e.*, 600 days plus 514 days), less the sum of the period calculated under Section 1.704(b) (*i.e.*, 302 days).

(iii) The '732 application is not subject to a terminal disclaimer.

(iv) Aside from the circumstances described in Section ii(2) *supra*, Applicants believe that there were no other circumstances under 37 C.F.R. § 1.704 constituting a failure by Applicants to engage in reasonable efforts to conclude processing or examination of the '732 application.

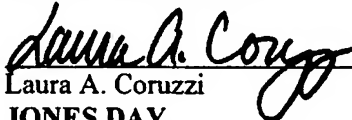
In summary, the total adjustment under 37 C.F.R. § 1.702(a) and (b) is 1,114 days, the total delay attributable to Applicants under 37 C.F.R. § 1.704 is 302 days, and thus the total period of adjustment due under 37 C.F.R. § 1.703(f) is believed to be 812 days. Accordingly, Applicants respectfully request an adjustment of patent term under 37 C.F.R. § 1.703(f) totaling 812 days.

Request for Reconsideration of Patent Term Adjustment Under 37 C.F.R. § 1.705(b)
Application No. 10/713,732

Applicants submit that the issues raised in this request for reconsideration of patent term adjustment are timely raised under 37 C.F.R. § 1.705(b), which provides in relevant part, that “[a]n application for patent term adjustment under this section *must be filed no later than the payment of the issue fee...*” (emphasis added). An Issue Fee Payment Authorization accompanies this Request, hence Applicants submit that the issues raised in this request are timely raised.

Respectfully submitted,

Date: June 12, 2009


Laura A. Coruzzi

30,742

(Reg. No.)

JONES DAY
222 East 41st Street
New York, New York 10017
(212) 326-3939

Enclosures

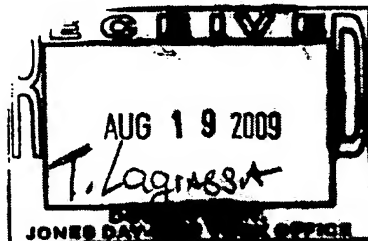
Exhibit D



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JONES DAY
222 EAST 41ST ST
NEW YORK NY 10017



MAILED

AUG 13 2009

OFFICE OF PETITIONS

In re Application of :
Palese, et al. :
Application No. 10/713,732 : ON APPLICATION FOR
Filed: November 14, 2003 : PATENT TERM ADJUSTMENT
Atty Docket No. 6923-118 :

This is in response to the REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b), filed June 12, 2009. Applicants submit that the correct patent term adjustment to be indicated on the patent is eight hundred twelve (812) days¹, not two hundred ninety-eight (298) days as calculated by the Office as of the mailing of the initial determination of patent term adjustment. Applicants request this correction solely on the basis that the Office will take in excess of three years to issue this patent.

As the instant application for patent term adjustment requests reconsideration of the patent term adjustment as it relates to the Office's failure to issue the patent within 3 years of the filing date, the application for patent term adjustment under 37 CFR 1.705(b) is **DISMISSED as PREMATURE**.

Knowledge of the actual date the patent issues is required to calculate the amount, if any, of additional patent term patentees are entitled to for Office failure to issue the patent within 3 years. See § 1.702(b). (This is true even in this instance where a request for continued examination (RCE) was filed.) The computer will not undertake the § 1.702(b) calculation until the actual date of issuance of the patent has been determined. Likewise, the computer will not calculate any further Office delay under § 1.702(a)(4) or applicant delay under § 1.704(c)(10) until the actual date of issuance of the patent has been determined. As such, the Office can not make a determination on the correctness of the patent term adjustment until the patent has issued.

¹ This calculation is based on a projected issuance date of October 6, 2009.

Application No. 10/713,732

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Requesting reconsideration of the patent term adjustment to be indicated on the patent under 37 CFR 1.705(b) based on the initial determination of patent term adjustment and a projected issuance date of the patent (or even the filing date of the request for continued examination) is premature. Accordingly, it is appropriate to dismiss as premature such a request.

Rather than file an application for patent term adjustment under 37 CFR 1.705(b) contesting the 37 CFR 1.702(b) calculation at the time of the mailing of the notice of allowance, applicants are advised that they may wait until the time of the issuance of the patent and file a request for reconsideration of the patent term adjustment pursuant to 37 CFR 1.705(d). As the USPTO does not calculate the amount of time earned pursuant to 37 CFR 1.702(b) until the time of the issuance of the patent, the Office will consider any request for reconsideration of the patent term adjustment due to an error in the calculation of 37 CFR 1.702(b) to be timely if the request for reconsideration is filed within two months of the issuance of the patent. However, as to all other bases for contesting the initial determination of patent term adjustment received with the notice of allowance, applicants must timely file an application for patent term adjustment prior to the payment of the issue fee¹.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e) for consideration of the application for patent term adjustment under 37 CFR 1.705(b).

Any request for reconsideration of the patent term adjustment indicated on the patent must be timely filed within 2 months after issuance pursuant to 37 CFR 1.705(d) and must include payment of the required fee under 37 CFR 1.18(e).

The Office of Data Management has been advised of this decision. This application is being referred to the Office of Data Management for issuance of the patent.

¹ For example, if applicant disputes both the calculation of patent term adjustment under 37 CFR 1.702(a)(1) for Office failure to mail a first Office action or notice of allowance not later than fourteen months after the date on which the application was filed and under 37 CFR 1.702(b) for Office failure to issue a patent within three years of the actual filing date of the application, then applicant must still timely file an application for patent term adjustment prior to the payment of the issue fee to contest the calculation of Office delay in issuing a first Office action or notice of allowance. See 37 CFR 1.705(b) and 35 U.S.C. 154(b)(3)(B). A dispute as to the calculation of the §1.702(a)(1) period raised on request for reconsideration of patent term adjustment under 37 CFR 1.705(d) will be dismissed as untimely filed.

Application No. 10/713,732

page 3

Telephone inquiries specific to this decision should be directed to Senior Petitions Attorney Shirene Willis Brantley at (571) 272-3230.

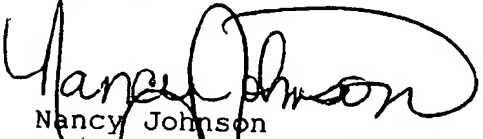

Nancy Johnson
Senior Petitions Attorney
Office of Petitions

Exhibit E

Electronically filed

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Patent No.	7,588,768 B2	Application No.:	10/713,732
Issued:	September 15, 2009	Filed:	November 14, 2003
Patentee:	Palese <i>et al.</i>	Attorney Docket No:	6923-118

For: ATTENUATED NEGATIVE
 STRAND VIRUSES WITH
 ALTERED INTERFERON
 ANTAGONIST ACTIVITY FOR
 USE AS VACCINES AND
 PHARMACEUTICALS

**REVISED REQUEST FOR RECONSIDERATION OF
PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The above-identified patent issued on September 15, 2009. According to the cover of the patent and the Issue Notification, the Patent Term Adjustment under 35 U.S.C. § 154(b) is 166 days.

In response to the PTO calculation of the Patent Term Adjustment of 166 days, and further to the Decision On Application For Patent Term Adjustment, mailed August 13, 2009 ("Decision"; a copy of which is submitted herewith as Exhibit A), Patentee hereby submits a Revised Request for Reconsideration of Patent Term Adjustment Under 37 C.F.R. § 1.705(b), originally filed on June 12, 2009 ("Original Request"; a copy of which is also submitted herewith as Exhibit B). Patentee submits the Revised Request in view of the issuance of the above-identified patent, whereas the Original Request was filed together with an authorization of payment of the Issue Fee and was thus based on an estimated patent issue date.

Patentee hereby respectfully requests reconsideration of the patent term adjustment indicated on the cover of the issued patent and in the Determination of Patent Term

NYI-4228446v1

Q00024677.036

Request for Reconsideration of Patent Term Adjustment Under 37 C.F.R. § 1.705(b)
 Patent No. 7,588,768 B2 (based on Application No. 10/713,732)

Adjustment under 35 U.S.C. § 154(b) ("Determination") mailed with the Issue Notification. Specifically, Patentee believes that the patent term adjustment of 166 days is not correct. The correct number of days for the patent term adjustment, for reasons explained below, should be, at a minimum, equal to the period starting January 14, 2005 and ending September 6, 2006 (600 days) plus the period starting November 15, 2006 and ending on April 11, 2008, the date that a request for continued examination (RCE) was filed (514 days) (see 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1)), minus 372 days consumed by Applicant delay (see 37 C.F.R. § 1.704(b)). Therefore, Patentee believes that the patent term adjustment should be, at a minimum, a total of 742 days.

A request for reconsideration of patent term adjustment under 37 C.F.R. § 1.705(b) must be accompanied by:

- (1) the fee set forth in 37 C.F.R. § 1.18(e); and
- (2) a statement of the facts involved, specifying:
 - (i) the correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment;
 - (ii) the relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) to which the patent is entitled;
 - (iii) whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and
 - (iv)(A) any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704; or
 - (B) that there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704.

See 37 C.F.R. § 1.705(b).

In support of this request, Patentee submits the following statement of facts:

1. Fee Required Under 37 C.F.R. § 1.705(b)(1)

Pursuant to 37 C.F.R. §§ 1.705(b)(1) and § 1.18(e), the fee required for filing this application is believed to be \$200.00. This fee was submitted with the Original Request filed

Request for Reconsideration of Patent Term Adjustment Under 37 C.F.R. § 1.705(b)
Patent No. 7,588,768 B2 (based on Application No. 10/713,732)

on June 12, 2009 and is acknowledged in the Decision. Therefore, Patentee seeks consideration of the Revised Request without payment of an additional fee. This Revised Request is submitted to update the Original Request, filed under 37 C.F.R. § 1.702(b), based on knowledge of the actual date that the patent has issued. No new grounds for reconsideration are presented.

However, if any additional fees are required, please charge them to Jones Day Deposit Account No. 50-3013 (referencing 702827-999117).

2. Statement Required Under 37 C.F.R. § 1.705(b)(2)

Pursuant to 37 C.F.R. § 1.702, Patentee submits the following statement of facts in support of this application:

- (i) The correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment are as follows:

1. Correct patent term adjustment:

The correct patent term adjustment is 742 days, which is attributable to (a) the failure of the PTO to mail a notification under 35 U.S.C. § 132 not later than fourteen months after the date of filing, under 35 U.S.C. § 111(a), of the application on which this patent is based, Application No. 10/713,732 (the " '732 application") (delay under 37 C.F.R. § 1.702(a)(1)) (the "A period") minus the number of actual calendar days occurring in both the A period and in the "B period" described below; and (b) the failure of the PTO to issue a patent within three years of the actual filing date of the '732 application (delay under 37 C.F.R. § 1.702(b)) (the "B period"), and minus the time consumed by Applicant delay as provided for in 37 C.F.R. § 1.704(b).

2. Bases under 37 C.F.R. § 1.702 for the adjustment:

(a) Delay under 37 C.F.R. § 1.702(a) (the "A period")

The delay by the PTO under 37 C.F.R. § 1.702(a) is 600 days.

As acknowledged by the PTO in its calculation of the patent term adjustment, the PTO failed to mail a notification under 35 U.S.C. § 132 within fourteen months from the date of filing of the '732 application. See PTO's Patent Application Information Retrieval page for U.S. Application No. 10/713,732 at Patent Term Adjustment History ("PTO PAIR Adjustment," Exhibit C, downloaded November 9, 2009). The '732 application was filed

Request for Reconsideration of Patent Term Adjustment Under 37 C.F.R. § 1.705(b)
 Patent No. 7,588,768 B2 (based on Application No. 10/713,732)

under 35 U.S.C. § 111(a) on November 14, 2003. The first notification under 35 U.S.C. § 132 (a Restriction Requirement) was mailed by the PTO on September 6, 2006. Accordingly, the PTO did not mail a notification under 35 U.S.C. § 132 or a notice of allowance under 35 U.S.C. § 151 within fourteen months after the date on which the application was filed (*i.e.*, by January 14, 2005), and thus, the delay under 37 C.F.R. § 1.702(a)(1) includes 600 days.

In sum, the number of days of delay in the A period, that is, under subsection (a)(1) of 37 C.F.R. § 1.702 is, at a minimum, 600 days.

(b) Delay under 37 C.F.R. § 1.702(b) (the "B period")

The delay by the PTO under 37 C.F.R. § 1.702(b) is 514 days.

The '732 application was filed under 35 U.S.C. § 111(a) on November 14, 2003. A patent based on this application issued on September 15, 2009. As provided for under 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1), the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed, not including the number of days in the period beginning on the date on which an RCE was filed and ending on the date the patent was issued. Therefore, in this case, the "B period" begins on November 15, 2006 and ends on April 11, 2008, the date that an RCE was filed (514 days). This delay in issuance of the patent was not included by the PTO in its calculation of patent term adjustment (*see* "PTO PAIR Adjustment," Exhibit C). Therefore, the total patent term adjustment for delay in issuance of the patent under the B period is 514 days.

(c) Overlapping Days in the Delay Periods

According to 35 U.S.C. § 154(b)(2)(A): "To the extent that periods of delay attributable to grounds specified in paragraph (1) *overlap*, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." *See* 35 U.S.C. § 154(b)(2)(A).

Patentee submits that there was no overlap of the actual calendar days of the A period, discussed in detail below, with the actual calendar days of the B period. Thus, the period of patent term adjustment on a patent that issues on the above-identified patent application is calculated as the sum of 600 plus 514, which is equal to 1,114 days (minus the time consumed by Applicant delay as discussed in Section ii below).

Request for Reconsideration of Patent Term Adjustment Under 37 C.F.R. § 1.705(b)
Patent No. 7,588,768 B2 (based on Application No. 10/713,732)

Patentee respectfully submits that under controlling case law, calculating the patent term adjustment is the result of summing the number of days of delay under 37 C.F.R. § 1.702(a) that do not comprise actual calendar days occurring in the B period (that is, the A period minus calendar days overlapping in both the A and B periods) and the number of days of delay under 37 C.F.R. § 1.702(b) (the B period). See *Wyeth v. Dudas*, 580 F.Supp.2d 138 (D.D.C. 2008) (hereinafter *Wyeth*), a copy of which is included here as Exhibit D.

In *Wyeth*, the Court held that “the only way that periods of time can ‘overlap’ is if they occur on the same day [and thus, if] an ‘A delay’ occurs on one calendar day and a ‘B delay’ occurs on another, they do not overlap.”

Turning to the '732 application, the period of delay under subsection (a)(1) of 37 C.F.R. § 1.702 includes the days of January 15, 2005 to September 6, 2006 (600 days). The delay under 37 C.F.R. § 1.702(b) comprises November 15, 2006 to April 11, 2008, the day on which an RCE was filed (514 days). Thus, the delay under 37 C.F.R. § 1.702(a)(1) occurring from January 15, 2005 to September 6, 2006 occurred on different calendar days than the delay under 37 C.F.R. § 1.702(b) (November 15, 2006 to April 11, 2008). Consequently, under 35 U.S.C. § 154(b)(2)(A), there are 600 days under 37 C.F.R. § 1.702(a) that do not overlap the 514 days of delay under 37 C.F.R. § 1.702(b) for the '732 application, and therefore the total delay under 37 C.F.R. § 1.702 for the adjustment should be a summation of the delays under 37 C.F.R. § 1.702(a) and 37 C.F.R. § 1.702(b), or 1,114 days (the sum of 600 and 514 days).

- (ii) The relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) and 37 C.F.R. § 1.704(b) are as follows:

- 1. Adjustment under 37 C.F.R. §§ 1.703(a) through (e):

An adjustment is sought under 37 C.F.R. § 1.703(a)(1), which provides, in relevant part, that the period of adjustment is “[t]he number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first.” In particular, Patentee seeks to include the delay under 37 C.F.R. § 1.702(a)(1) occurring from

Request for Reconsideration of Patent Term Adjustment Under 37 C.F.R. § 1.705(b)
Patent No. 7,588,768 B2 (based on Application No. 10/713,732)

January 15, 2005 to September 6, 2006 (600 days) that occurred on different calendar days than the delay under 37 C.F.R. § 1.702(b).

An adjustment is sought under 37 C.F.R. § 1.703(b), which provides, in relevant part, that "the period of adjustment under 37 C.F.R. § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) ... and ending on the date a patent was issued ... not including ... [t]he number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date the patent was issued."

Patentee submits that this period consists of 514 days for the period beginning the day after November 14, 2006 (the date that is three years after the date on which the '732 application was filed) and ending on the day that an RCE was filed, April 11, 2008.

Patentee further submits that the 600 actual calendar days of delay under 37 C.F.R. § 1.702(a) do not overlap the any of the 514 actual calendar days of delay under 37 C.F.R. § 1.702(b), as explained above.

Accordingly, Patentee believes that the delays attributable to PTO delay under 37 C.F.R. § 1.702 total 1,114 days.

2. Adjustment under 37 C.F.R. § 1.704(b):

As discussed in section (i) above, Patentee believes that the total delay by the PTO under 37 C.F.R. § 1.702(a) and (b) amounts to 1,114 days.

In the PTO PAIR Adjustment, the PTO determination the Applicant delay to be a period of 434 days. Patentee respectfully disagrees with this determination, and believes that the delay attributable to Applicants under 37 C.F.R. § 1.704(b) is 372 days, for the reasons set forth below.

Patentee accepts the determination of the 302 days of Applicant delay until March 4, 2009 set forth on the PTO PAIR Adjustment. A Notice of Allowance was mailed on March 13, 2009, so all subsequent determinations of Applicant delay should be under 37 C.F.R. § 1.704(c)(10) (stating, in relevant part, that for a submission of a paper "after a notice of allowance has been mailed," "the period of adjustment set forth in 1.703 shall be reduced by ... [t]he number of days, if any, beginning on the date the ... other paper was filed and ending on the mailing date of the ... notice in response to the ... other such paper"). According to the PTO PAIR Adjustment, it appears that the PTO determined that there were

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68 days of Applicant delay from the period beginning on the date of filing of an alleged "Miscellaneous Incoming Letter" on May 7, 2009 and ending on July 14, 2009, the day a second alleged Miscellaneous Incoming Letter was filed (the "2nd Letter"). Patentee believes that this determination is in error, because the period of delay should have been calculated from the period beginning the day the alleged Miscellaneous Incoming Letter was filed and ending on May 12, 2009, the date the PTO mailed a response to the Miscellaneous Incoming Letter, *i.e.*, 6 days. Specifically, according to the file history of the '732 application, the May 7, 2009 filing by Applicants consists of a Petition to Expunge Proprietary or Trade Secret Material Pursuant to 37 C.F.R. § 1.59 and its transmittal, a Submission of Proprietary or Trade Secret Material Pursuant to MPEP § 724 (collectively, the "Petition"; a copy of the Petition from the file history is submitted herewith as Exhibit E). A Decision on the Petition was mailed by the PTO on May 12, 2009 (a copy of which is submitted herewith as Exhibit F). Thus, Patentee believes that the period of delay for submission of the Petition should not have ended on the date the 2nd Letter was filed but rather should have ended on the date the Decision on the Petition was mailed (May 12, 2009), *i.e.*, 6 days.

Patentee accepts the PTO determination, in the PTO PAIR Adjustment, of the Applicant delay of 64 days in connection with the filing of the 2nd Letter on July 14, 2009, based on the understanding that the delay was calculated as the number of days in the period beginning the day after July 14, 2009, when the 2nd Letter was filed, and ending on September 15, 2009, the day that the patent issued.

It is also respectfully noted that according to the PTO PAIR Adjustment, a Statement Indicating a Loss of Entitlement to Small Entity Status ("statement") was filed on June 12, 2009. Patentee wishes to point out that no such statement was filed on June 12, 2009. Rather, a Request for Reconsideration of Patent Term Adjustment was filed on June 12, 2009, which does not contribute to Applicant delay. *See* 37 C.F.R. § 1.704(e).

Patentee thus believes that the delay attributable to Applicants under 37 C.F.R. § 1.704(b) is 302 days, plus 6 days, plus 64 days, *i.e.*, 372 days, and not 434 days as calculated by the PTO. Therefore, Patentee believes that the total period of adjustment due under 37 C.F.R. § 1.703(f) is 1,114 days minus 372 days, *i.e.*, 742 days, not the 166 days calculated by the PTO. This total period is the sum of the periods of delay by the PTO calculated under 37 C.F.R. §§ 1.702(a) through (e) (*i.e.*, 600 days plus 514 days), less the sum of the period calculated under Section 1.704(b) (*i.e.*, 372 days).

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- (iii) The '732 application is not subject to a terminal disclaimer.
- (iv) Aside from the circumstances described in Section ii(2) *supra*, Patentee believes that there were no other circumstances under 37 C.F.R. § 1.704 constituting a failure by Applicants to engage in reasonable efforts to conclude processing or examination of the '732 application.

In summary, the total adjustment under 37 C.F.R. § 1.702(a) and (b) is 1,114 days, the total delay attributable to Applicants under 37 C.F.R. § 1.704 is 372 days, and thus the total period of adjustment due under 37 C.F.R. § 1.703(f) is believed to be 742 days. Accordingly, Patentee respectfully requests an adjustment of patent term under 37 C.F.R. § 1.703(f) totaling 742 days.

Patentee submits that the issues raised in this revised request for reconsideration of patent term adjustment are timely raised. In particular, this request is in compliance with 37 C.F.R. § 1.705(b) and 37 C.F.R. § 1.705(d), the latter of which provides in relevant part, that "[i]f there is a revision to the patent term adjustment indicated in the notice of allowance, the patent will indicate the revised patent term adjustment . . . [and] any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued" This is consistent with the Decision, in which Patentee was informed that "[a]ny request for reconsideration of the patent term adjustment indicated on the patent must be timely filed within 2 months after issuance pursuant to 37 CFR 1.705(d)" Since the date two months from the September 15, 2009 issue date falls on a Sunday, this request for reconsideration of patent term adjustment is timely filed on November 16, 2009.

Respectfully submitted,

Date: November 16, 2009

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Enclosures

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